July 30, 2019

Ms. Leigh Purvis
Director of Health Services Research
AARP
601 E Street NW
Washington, DC 20049

Dear Ms. Purvis:

Thank you for appearing before the Subcommittee on Health on Thursday, May 9, 2019 at the hearing entitled "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain." We appreciate the time and effort you gave as a witness before the Subcommittee.

Pursuant to Rule 3 of the Committee on Energy and Commerce, members are permitted to submit additional questions to the witnesses for their responses, which will be included in the hearing record. Attached are questions directed to you from certain members of the Committee. In preparing your answers to these questions, please address your responses to the member who has submitted the questions using the Word document provided with this letter.

To facilitate the publication of the hearing record, please submit your responses to these questions by no later than the close of business on Friday, August 9, 2019. As previously noted, this transmittal letter and your responses will be included in the hearing record. Your written response should be transmitted by e-mail in the Word document provided with this letter to Josh Krantz, Policy Analyst with the Committee, at josh.krantz@mail.house.gov. You do not need to send a paper copy of your responses to the Committee. Using the Word document provided for submitting your responses will also help maintain the proper format for incorporating your answers into the hearing record.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please have your staff contact Mr. Krantz at (202) 225-5056.

Sincerely,

Frank Pallone, Jr.
Chairman

Attachments

cc: Hon. Greg Walden, Ranking Member
Committee on Energy and Commerce

Hon. Anna G. Eshoo, Chairwoman
Subcommittee on Health

Hon. Michael C. Burgess, Ranking Member
Subcommittee on Health

Attachments—Additional Questions for the Record

Subcommittee on Health
Hearing on
"Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"
May 9, 2019

Leigh Purvis

The Honorable Michael C. Burgess, M.D.

1. Something I find particularly concerning about our drug supply chain is the possibility of drug shortages. These can occur because of natural disasters, manufacturing issues, or business decisions. What are each of your respective companies doing to prevent drug shortages?

2. Yesterday, the Administration released a rule requiring manufacturers to include drug prices in direct-to-consumer (DTC) advertisements. This would shine a light on manufacturer drug pricing strategies and provide consumers more information about their prescription drug options. What would the effect of this type of price transparency have on Blue Cross Blue Shield and the overall market?

The Honorable John Shimkus

1. Given that most of the witnesses on the panel have referenced the role of creating value in the health care supply chain, please comment on: Existing areas where Congress or the Administration may have needlessly added to the cost that patients or the government pays for a particular product, service, or intervention. For example, do you have recommendations on how reforms to existing laws like Stark and the Anti-Kickback Statute could accelerate value-based contracting within Medicare and Medicare Advantage?

2. How do we ensure that these value-based reforms benefit patients and protect taxpayers?

Leigh Purvis's Response:

AARP supports efforts to move towards value-based care, including aligning the price of a drug with the value that it provides rather than continuing to allow drug manufacturers to set prices on

the basis of what the market will bear. While AARP broadly supports the concepts behind value-based purchasing arrangements, we also recognize that implementation may be challenging.

For example, AARP is aware that there is no universal definition of value, nor is there consensus on the standards and data that should be used when evaluating the value of prescription drugs. AARP is also concerned by research indicating that there is little evidence that value-based purchasing results in lower spending or better quality for patients.[1] As such, we urge Congress to carefully consider the use of value-based purchasing tools and ensure that they are only utilized when there is strong clinical evidence to support their use.

AARP also urges that any value-based purchasing arrangements share savings with beneficiaries directly, such as automatically reducing cost-sharing for beneficiaries who are taking the affected drugs.

In addition, AARP strongly believes that robust consumer safeguards must be included in efforts to pursue value-based purchasing arrangements for prescription drugs. Appeals processes should be transparent, easy-to-understand, and fair in order for them to function as a true recourse for enrollees. Congress should also regularly revisit and modify processes as needed to ensure appropriate beneficiary access.

We also recommend that Congress establish a transparent, comprehensive, and publicly available monitoring process for any value-based purchasing agreements. As part of the monitoring process, AARP encourages Congress to identify formal procedures for regularly engaging and involving beneficiaries and their advocates, including tools such as patient experience surveys and focus groups.

Further, given that value-based purchasing agreements are intended to help reduce prescription drug and taxpayer spending, AARP believes that any new prescription drug payment model should allow for lower reimbursement for drugs that are less effective than comparable drugs. In addition, higher reimbursement should be based on clear and convincing evidence that a drug is significantly more effective.

AARP also remains mindful that value-based purchasing agreements remain in their infancy and that meaningful savings could take years or decades to materialize.[2] Consequently, AARP continues to believe that additional administrative and legislative reforms are needed in order to reduce drug costs for beneficiaries and taxpayer-funded public programs. Such reforms could include secretarial negotiation, allowing for the safe importation of prescription drugs from Canada and other select nations, and curtailing anti-competitive behaviors that deter generic entry into the market.

The Honorable Gus M. Bilirakis

[1] E. Seeley and A. S. Kesselheim, *Outcomes-Based Pharmaceutical Contracts: An Answer to High U.S. Drug Spending?* The Commonwealth Fund, September 2017.
[2] N. Bisserbe, "For new Trump Drug Plan, a Cautionary Tale in Italy," Wall Street Journal, April 17, 2018.

1. With Florida's traditionally higher senior and Veteran populations, lowering prescription drug prices is very important to me.

    - To that end, Florida recently passed a law to allow for prescription drug importation. Can you discuss the benefits and risks of prescription drug importation-assuming Federal approval, what can Florida do to best position itself for success?

Leigh Purvis's Response:

AARP supports the safe, legal importation of less expensive prescription drugs from Canada and other countries as one step that will help lower costs and add competitive pressure on drug makers to lower the prices they set in the U.S.

According to Food and Drug Administration (FDA), the US imports more than 40 percent of its finished drugs and 80 percent of its active pharmaceutical ingredients.[3] In addition, FDA has repeatedly and safely imported drugs from other countries in response to US drug shortages.[4] Further, the agency recently proposed a single global development program that would allow for simultaneous drug approvals by multiple regulators,[5] an extremely strong indication that other countries have equally safe regulatory systems.

AARP is also mindful that most of the concerns about drug importation are based on individuals who purchased drugs from questionable websites. Florida's new law would ensure that FDA is appropriately engaged in the importation process and could actually help reduce such events by ensuring that struggling patients can purchase less expensive but equally safe and effective imported drugs at their usual pharmacy.

AARP strongly supported bipartisan legislation in Florida, Colorado, Maine, and Vermont to allow importation in those states. We believe it is critical that states that pass such legislation work closely with FDA to ensure that these laws can take effect in a manner that safely achieves the savings that were intended and makes prescription drugs more affordable and accessible to older Americans.

Finally, AARP is aware that the FDA has long had the authority to approve importation plans but only done so under limited circumstances. Consequently, we were pleased that the Trump Administration has agreed that lower priced drugs can be safely imported and that the FDA should use its full authority under law to help American consumers.

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[3] https://www.fda.gov/vaccines-blood-biologics/international-activities/foreign-inspectional-collaborations
[4] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm292658.htm
[5] https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/advancing-toward-goal-global-approval-generic-drugs-fda-proposes-critical-first-steps-harmonize